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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/682,094

10/09/2003

Poul Bach

10313-US-NP

9214

25908

7590

04/27/2012

NOVOZYMES NORTH AMERICA, INC.

500 FIFTH AVENUE

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NEW YORK, NY 10110

EXAMINER

METZMAIER, DANIEL S

ART UNIT

PAPER NUMBER

1762

NOTIFICATION DATE

DELIVERY MODE

04/27/2012

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/682,094	<b>Applicant(s)</b> BACH ET AL.	
	<b>Examiner</b> DANIEL S. METZMAIER	<b>Art Unit</b> 1762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2012.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1-16, 18-20, 27-34, 38 and 40-43 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1-16, 18-20, 27-34, 38 and 40-43 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### DETAILED ACTION

Claims 1-16, 18-20, 27-34, 38 and 40-43 are pending.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 31-34 and 42-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Basis for the claimed limitation, “the starting material **is not substantially dissolved** however characterized as a fully water soluble material”, has not been pointed out in the response (Response, filed 19 Jan. 2012) and the examiner has been unable to find adequate basis in the original disclosure for said limitation.

**Claims 31-34 and 42-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of contacting either dispersible materials with water, oil or aqueous liquids; or fully water soluble particulate materials contacted with oil; does not reasonably provide enablement for making particulate compositions by contacting a particulate starting material that is fully water soluble material (see independent claims) with liquid, e.g., water and aqueous liquid (claims**

**13 and 14 or Spec., p. 11, l. 28), to form a mixture that results in a particulate composition.**

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The following *Wands* factors included in the analysis are the proper basis for a conclusion of the non-enabled subject matter.

(A) The breadth of the claims: The claims are generic to the liquid as water or aqueous liquid. See the original specification (Spec., p. 11, l. 28). The claims are further generic to numerous additional ingredients other than the enzyme;

(B) The nature of the invention: the claims are directed to methods of preparing enzyme granules;

(C) The state of the prior art: the prior art discloses unknown number of enzymes, which would be expected to have diverse and varies water solubility.

(D) The level of one of ordinary skill: the level of one having ordinary skill in the art is varied to include chemical technicians to PhD chemist;

(E) The level of predictability in the art: the art is material dependent since the solubility of the particles is dependent on a number of factors (e.g., type of enzyme, additives, temperature, type of liquid, etc.);

(F) The amount of direction provided by the inventor: the specification does not list a single specific example but list certain classes, e.g., enzymes.

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There is no disclosure of a specific enzymes and/or enzyme compositions having the solubility properties as now claimed;

(G) The existence of working examples: no specific example for the claimed enzyme species is set forth.

The instant examples disclose starting particulate materials including sodium sulfate with a number of other additives including but not limited to starch, cellulose, dextrin, and sorbitol with water as the liquid. The only starting material characterized with a particle size is the sodium sulfate. The solubility of sodium sulfate is ~ 28.1 grams / 100 ml water @ 25 °C. The instant example 1 employs a mixture comprising 20 Kg of sodium sulfate in 5000 g of water. This equates to 80 wt % of, which is well above the solubility of said sodium sulfate (*e.g.*, example 1 has a mixture comprising 20 Kg sodium sulfate in 5000 g of water or 80 wt % of sodium sulfate in water). Assuming the examples are done at about room temperature, said exemplified material is not a **fully water soluble material** as now claimed; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure is undue since it is unclear what particles are both fully water soluble and not substantially dissolved in liquid (*i.e.*, water or aqueous liquid) to form said enzyme particulates.

It would require an undue amount of experimentation on the part of the ordinary skilled artisan to determine the method components and parameters. In the case \*\*\*. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicants process steps read on dissolution of enzyme solute materials in water or aqueous liquid, *i.e.*, dissolved and non-particulate. Applicants' specification does not adequately describe how to carry out the methods wherein the particulate starting materials is fully soluble in water when water or aqueous liquid is the liquid.

**The following is a quotation of the second paragraph of 35 U.S.C.**

**112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 10, 31-34 and 42-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 10 sets forth the limitation, wherein "the enzyme-granules comprise an active compound". It is unclear for what the "active compound" is intended to be "active".

Applicants' preamble in the independent claims 31 and 34 are inconsistent with the scope of the claimed subject matter sought for patent or the claims are incomplete regarding the method of preparing a particulate material. It is unclear how a particulate starting material that is **fully water soluble material** (see independent claims) and is mixed with liquid, *e.g.*, **water and aqueous liquid** (claims 13 and 14), to form a mixture can possibly result in a particulate composition without some other processing step.

The claims are generic to the liquid as water or aqueous liquid. See the original specification (Spec., p. 11, l. 28). Applicants claims do not specify the conditions the particulate materials is a **fully water soluble material**.

Furthermore, it is unclear how applicants define the terms: **fully water soluble**. It is unclear what conditions said particles are fully water soluble.

Applicants set forth water solubility as:

Water soluble:

“Water soluble” **particulate materials or fractions of materials** in the context of the present invention are understood to be particulate materials of fractions of materials of which at least 50 g/l and more particularly, at least 80 g/l dissolve in water at a temperature of 30°C. (emphasis added).

It is further unclear what fractions of particulate materials make up the “at least 50 g/l and more particularly, at least 80 g/l dissolve in water at a temperature of 30°C”. The concentrations of 50 g/ l and 80 g/l equate to 5 wt % and 8 wt %, respectively.

**The following is a quotation of the fourth paragraph of 35 U.S.C. 112:**

Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 11 is rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. It is unclear how claim 11 to enzyme granules comprise one or

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more enzymes further limits the enzyme granules of claim 1, Which necessarily requires one or more enzymes to be the claimed enzyme granule. Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-7, 10-16, 27-30, 38 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simonsen, US PG PUB 2002/0119201<sup>1</sup>, in view of Markussen et al, US 4,106,991.**

Simonsen (examples, especially example 1) discloses coating enzyme granulates. Said enzyme granulates are produced according to a modified method of example 1 of US 4,106,991 (to Markussen et al) and coated by the method of example 22 of US 4,106,991. Said enzyme granulates comprise Savinase (a protease), sodium sulfate (*i.e.*, salt), carbohydrate binder (Glucidex) and methionine (antioxidant).

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<sup>1</sup> Simonsen, US PG PUB 2002/0119201, qualifies as prior art under 35 U.S.C. 102(b) since the Provisional Application No. 60/417,577, filed on 10 October 2002, lacks adequate support for the claims as now claimed. Specifically, 60/417,577 lacks support for the limitation, "wherein more than 80% of the particles in the particulate starting material remain un-agglomerated". Therefore, the claims of Application No. 10/682,094 have the filing date of 09 October 2003.

Markussen et al (example 1) produces enzyme granulates having an average particle diameter of 600  $\mu\text{m}$ . Markussen et al (example XXII or 22) discloses further sieving granulates to obtain granulates in the range of 300 to 840  $\mu\text{m}$ .

Simonsen ([0092]) disclose application of lubricant reduces dusting and risk of breakage (*i.e.*, higher average particle strength) and that particle agglomeration can be inhibited by powdering with a dry particulate or significantly prevented by lowering the amount of lubricant to less than 1 w/w % of the lubricated granule.

These references are combinable because Markussen et al is specifically referenced in the Simonsen reference. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to vary the lubricant amount to values less than 1 w/w % taught in Simonsen to substantially prevent agglomeration. The claimed liquid amount of "not exceeding 20 % by weight" reads on the Simonsen liquid lubricant amount of less than 1 w/w %.

It is reasonable to expect that the limitation, "wherein more than 80% of the particles in the particulate starting material remain un-agglomerated", reads on and/or is at least suggested by the Simonsen characterization to prevent significant agglomeration ([0092]). Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality for a result-effective variable, *i.e.*, a variable which achieves a recognized result. The amounts of the lubricant, powdering agents (*i.e.*, anti-

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agglomerating agents) and process temperatures are clearly taught as result-effective variables.

**Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simonsen, US PG PUB 2002/0119201<sup>2</sup>, in view of Markussen et al, US 4,106,991, as applied to claims 1-7, 10-16, 27-30, 38 and 40-41 above, and further in view of Lödige et al, US 3,027,102.**

Simonsen in view of Markussen et al discloses coating enzyme granulates as set forth in the preceding rejection. The citations and reasoning is herein incorporated by reference.

Markussen et al (6:18-26) disclose mixers as shown in US 3,027,102 to Lödige et al as the equipment useful in the disclosed methods.

Lödige et al disclose high shear mixers. Applicants (page 16, lines 29-32; examples at 19:10; 20:7-8; and 21:10-11) disclose the use of Lödige mixers.

These references are combinable because Lödige et al is specifically referenced in the Markussen et al as suitable mixing apparatus. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to vary the mixing speeds of the Lödige et al mixing apparatus.

The references teach compounds of claims 13-16 and the degree of comminution is dependent on the shear rate and the materials sheared during mixing. Merely modifying the process conditions is not a patentable modification

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<sup>2</sup> Simonsen, US PG PUB 2002/0119201, qualifies as prior art under 35 U.S.C. 102(b) since the Provisional Application No. 60/417,577, filed on 10 October 2002, lacks adequate support for the claims as now claimed. Specifically, 60/417,577 lacks support for the limitation, "wherein more than 80% of the particles in the particulate starting material remain un-agglomerated". Therefore, the claims of Application No. 10/682,094 have the filing date of 09 October 2003.

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absent a showing of criticality for a result-effective variable, *i.e.*, a variable which achieves a recognized result.

**Claims 8, 9 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simonsen, US PGPUB 2002/0119201<sup>3</sup>, in view of Markussen et al, US 4,106,991, and Lödige et al, US 3,027,102, as applied to claims 1-7, 10-16, 18, 27-34, 38 and 40-41 above, and further in view of Novozymes A/S, WO 01/23513 A1<sup>4</sup>.**

Simonsen in view of Markussen et al and Lödige et al discloses coating enzyme granulates as set forth in the preceding rejection. The citations and reasoning is herein incorporated by reference.

Simonsen in view of Markussen et al and Lödige et al differ from claims 8 and 9 in the explicit characterization of the density of the core materials to be coated.

Novozyymes A/S '513 (abstract; page 1: lines 4 et seq) compositions comprising solid particles dispersed therein, which are wax materials having an active components distributed therein. Novozymes A/S '513 (2 to 3: 35 to 4) teaches the desire to inhibit agglomeration. Novozymes A/S '513 (4:17-22) disclose the advantages of lowering dusting and toxicity of the actives by coating said actives. Novozymes A/S '513 (5 to 6:35 to 2) teach as an example particles of 1.5 g/cm<sup>3</sup> to 2.5 g/cm<sup>3</sup>.

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<sup>3</sup> Simonsen, US PGPUB 2002/0119201, qualifies as prior art under 35 U.S.C. 102(b) since the Provisional Application No. 60/417,577, filed on 10 October 2002, lacks adequate support for the claims as now claimed. Specifically, 60/417,577 lacks support for the limitation, "wherein more than 80% of the particles in the particulate starting material remain un-agglomerated". Therefore, the claims of Application No. 10/682,094 have the filing date of 09 October 2003.

Novozymes A/S '513 (7:17-21; and 9:10-20) disclose waxes include polyethylene glycols (PEG), such as PEG 1500 or PEG 4000. Novozymes A/S '513 (11:7 et seq, especially 27 et seq) disclose enzymes as actives.

Novozymes A/S '513 (25:17-35) disclose the conventional steps of sieving and separating undesirable particles. Novozymes A/S '513 (example 1, 40:32-33) disclose materials having a true density of 1.25 g/ml, which is more than twice the bulk density of 0.54 g/ml.

These references are combinable because they teach granular enzyme products. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ starting enzymes having a true density of at least 1.3 g/cm<sup>3</sup> or at least 1.5 g/cm<sup>3</sup> as taught in the Novozymes A/S '513 reference as conventional functional equivalents for the advantages taught in the Novozymes A/S '513 reference.

The references teach compounds of claims 13-16 and the degree of comminution is dependent on the shear rate and the materials sheared during mixing. Merely modifying the process conditions is not a patentable modification absent a showing of criticality for a result-effective variable, *i.e.*, a variable which achieves a recognized result.

### ***Response to Arguments***

Applicant's arguments filed 19 January 2012 have been fully considered but they are not persuasive.

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<sup>4</sup> Cited in Applicants' PTO-1449 form, filed 09 October 2003.

(I) Applicants (Response, p. 7, Item I) assert regarding claims 1-16, 18-20, 27-38 and 40-43: "No undue experimentation would be required to understand material may be characterized as fully water soluble, however still have a solid form." Applicants' assertions have not been deemed persuasive for claims 31-34 and 42-43 for the reasons set forth herein above.

Applicants' assertions are moot regarding claims 35-37, which have been canceled. Applicants' assertions are moot regarding claims 1-16, 18-20, 27-30, which have been amended to delete the "fully water soluble" limitation.

(II) Applicants (Response, p. 7, Item II) assert regarding claims 1-16, 18-20, 27-38 and 40-43 said claims are clear. Applicants' assertions regarding claims 10, 31-34 and 42-43 have been addressed in the rejections herein above.

Applicants' assertions are moot regarding claims 1-16, 18-20, 27-30, which have been amended to delete the "fully water soluble" limitation.

(Applicants assert the examiner has not made out a prima facie case of obviousness.

(III) The rejection of claim 15 under 35 USC 112, 2<sup>nd</sup> ¶, has been withdrawn withdrawn in view of the claim amendments (filed 19 January 2012).

(IV)-(V) The rejection by and/or over James et al has been withdrawn in view of the claim amendments (filed 19 January 2012).

(VI)-(IX) The rejections over Simonsen, US PG PUB 2002/0119201, in view of Markussen et al, US 4,106,991; Lödige et al, US 3,027,102; and Novozymes A/S, WO 01/23513 A1; have been maintained as set forth above.

Applicants' remaining arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Appel et al, US 5,164,108 and US 5,133,924, are deemed particularly relevant since they teach methods of treating particulate materials to high shear apparatus (*e.g.*, Lödige CB 30 recycler and KM 300 mixer, Shugi Granulator, Drais K-TTP 80 and K-T 160 (see US '108 4:18-36 and 5:30-39; or '924 5:1-25 and 5 to 6:65 to 6)) for the advantage of increasing the density thereof.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL S. METZMAIER whose telephone number is (571)272-1089. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David W. Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/DANIEL S. METZMAIER/  
Primary Examiner, Art Unit 1762**

DSM